

K073238

Section 8

Pg. 1 of 3

510(k) - Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. GENERAL INFORMATION

JAN - 3 2006

1. Device Name and Classification

Product Name: **syngo® Volume Perfusion-CT Neuro**
Classification Name: Accessory to Computed Tomography System
Classification Panel: Radiology
CFR Section: 21 CFR §892.1750
Device Class: Class II
Product Code: 90 JAK

2. Importer/Distributor Establishment:**Registration Number: 2240869**

Siemens Medical Solutions, Inc.
51 Valley Stream Pkwy
Malvern, PA 19355

3. Manufacturing Facility:

Siemens AG
Medical Solutions
Henkestrasse 127
D-91052 Erlangen, Germany

4. Contact Person:

Mr. Ralf Hofmann
Regulatory Affairs Specialist
Siemensstr.1; D-91301 Forchheim
Phone: +49 9191 18-8170
Fax: +49 9191 18-9782

5. Date of Preparation of Summary: Oct 12th 2007

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

6. General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

7. Substantial Equivalence:

The **syngo® Volume Perfusion-CT Neuro** software package that is addressed in this premarket notification, is substantially equivalent to the following commercially available software package

<u>Manufacturer</u>	<u>Product</u>	<u>510(k)</u>	<u>Clearance date</u>
1. Siemens	syngo Perfusion-CT	K033832	12/23/2003
2. Siemens	syngo Perf. CT Body	K050867	04/14/2005
3. General Electric	CT Perfusion 4	K052839	03/10/2006

8. Device Description and Intended Use:

syngo® Volume Perfusion-CT Neuro is a post-processing software package, which runs on an Intel-based PC platform designed to post-process images acquired with SOMATOM CT scanners, which meet certain minimal requirements (i.e. Siemens Definition, Sensation 64, ...). It is a package containing evaluation software that supports the evaluation of Dynamic CT data gathered after the injection of a compact bolus of contrast media, where the contrast media acts as a pure intravascular tracer.

The Siemens **syngo® Volume Perfusion-CT Neuro** software package has been designed to evaluate areas of brain perfusion. The software can calculate cerebral blood flow (CBF), cerebral blood volume (CBV), local bolus timing (i.e. time to start, time to peak), mean transit time (MTT), and vascular permeability (blood brain barrier disturbances) from sets of images or volumes reconstructed from continuously acquired CT data after the injection of contrast media. The package also allows the calculation of mirrored regions or volumes of interest and the visual inspection of time attenuation curves.

One clinical application is to visualize the apparent blood perfusion in brain tissue affected by acute stroke. Areas of decreased perfusion, as is observed in acute cerebral infarcts, appear as areas of changed signal intensity (lower for CBF and CBV, higher for time to peak and MTT).

Syngo® Volume Perfusion-CT Neuro supports the physician in identifying areas of decreased perfusion which indicate the occurrence of acute stroke during the first 6 hours after onset of symptoms.

A second application is the visualization of the permeability. It is used for the modeling of extra-vascular leakage of blood into the interstitial space. This additional capability can display blood brain barrier disturbances and thus may improve the differential diagnosis of brain tumors and be helpful in therapy monitoring.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 3 2008

Siemens AG Medical Solutions
% Mr. Olaf Teichert
Responsible Third Party Official
TÜV SÜD America
1775 Old Hwy 8 NW, Ste 104
NEW BRIGHTON MN 55112-1891

Re: K073238

Trade/Device Name: syngo® Volume Perfusion-CT Neuro
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: December 10, 2007
Received: December 14, 2007

Dear Mr. Teichert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for use

510(k) Number (if known):

K073238

Device Name:

syngo® Volume Perfusion-CT Neuro

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and
Radiological Devices
510(k) Number K073238